

In the Drawings:

Please replace FIGS. 8 and 15 with the replacement Figures filed herewith. Such Figures have been amended simply to add Sequence Identifiers to sequences disclosed therein. Therefore, Applicants respectfully submit that no substantial changes have been made to the application, and that such amendments do not constitute new matter. Entry thereof is respectfully requested.

## **REMARKS**

This is meant to be a complete response to the Office Action mailed March 23, 2007. In the Office Action, the Examiner stated that the application failed to comply with the requirements of 37 CFR 1.821 and 1.825. The Examiner also objected to: (1) the disclosure for containing sequences not identified with proper sequence identifiers; (2) the amendment filed 5/24/04 under 35 U.S.C. 132(a); (3) the abstract for not describing the claimed invention; (4) the disclosure because of informalities; and (5) claims 6, 7, 37, 51, 68 and 82 because of spelling errors. The Examiner rejected claims 3, 4, 33, 34, 64 and 65 under 35 U.S.C. 112, first paragraph (written description), and claims 3, 4, 7, 21, 33, 34, 37, 64, 65, 68 and 2 under U.S.C. 112, first paragraph (enablement). The Examiner also rejected Applicants' claims 1-7, 12-17, 19-21, 30-37, 42-51, 60-68, 73-82, 91 and 92 under 35 U.S.C. 112, second paragraph. Further, the Examiner rejected claims 1-7, 12, 13, 30-37, 42, 43, 60 and 61 under 35 U.S.C. 102(b) as being anticipated by US 5,482,841; and claims 1-7, 12, 13, 30-37, 42, 43, 60 and 61 under 35 U.S.C. 102(e) as being anticipated by US 5,482,841. The Examiner also rejected Applicants' claims 1-7, 12, 13, 30-37, 42, 43, 60-68, 73-82, 91 and 92 under 35 U.S.C. 103(a) as being unpatentable over US5,482,841 in view of US5,292,641; and claims 1-7, 12, 13, 30-37, 42, 43, 60-68, 73-82, 91

and 92 under 35 U.S.C. 103(a) as being unpatentable over US5,482,841 in view of US5,292,641, Prilliman et al. (Immunogenetics, 45:379-385 (1997)), DiBrino et al. (Biochemistry, 34:10130-10138 (1995)) and US6,232,445. Finally, the Examiner provisionally rejected claims 62-68, 73-82, 91 and 92 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-34, 39-44, 46-52, 54-56, 57-63, 68-73, 75-81 and 83-112 of copending Application No. 10/902,400 in view of US5,482,841.

Amendments to/Status of the Claims

The claims have been amended herein to cancel claims 1-30, 43, 44, 52-59 and 62-92, without prejudice.

The remaining independent claim, claim 31, has been amended herein to include all of the limitations of dependent claim 44.

Claims 31-42 and 45-51 are currently pending in the subject application. Claims 38-41 are currently withdrawn; however, upon allowance of any of claims 31-37, 42 and 45-51, Applicants respectfully request rejoinder and reconsideration of currently withdrawn claims 38-41.

Sequence Listing

In the Office Action, the Examiner stated that the application failed to comply with the requirements of 37 CFR 1.821 and 1.825,

and objected to the disclosure for containing sequences not identified with proper sequence identifiers.

In response to the objection, replacement Figures 8 and 15 are submitted herewith. Such Figures have been amended herein to add sequence identifiers to the sequences originally disclosed therein.

In addition, a Sequence Listing has also been submitted herewith in paper and CRF forms; such Sequence Listing contains the sequences originally disclosed in Figures 8 and 15.

Applicants respectfully submit that the amendments to Figures 8 and 15 and the addition of the Sequence Listing do not constitute new matter. Entry thereof is respectfully solicited.

In view of the above, Applicants respectfully submit that the application fully complies with the requirements of 37 CFR 1.821 and 1.825. Applicants respectfully request reconsideration and withdrawal of the objection to the disclosure for the sequences disclosed without appropriate sequence identifiers.

Applicants' Response to the Objections to the Disclosure and Claims

In the Office Action, the Examiner objected to: (1) the amendment filed 5/24/04 under 35 U.S.C. 132(a); (2) the abstract for not describing the claimed invention; (3) the disclosure because of

informalities; and (4) claims 6, 7, 37, 51, 68 and 82 because of spelling errors.

In response to (1) above, paragraph [0001] has been amended herein such that the incorporation by reference of provisional application US Serial No. 60/474,655 has been removed. However, Applicants respectfully submit that the benefit claim of US Serial No. 60/474,655 is still valid.

In response to (2) above, a replacement abstract has been submitted herein that describes the claimed invention.

In the objection under (3) above, the Examiner stated that the disclosure was objected to because of the following informalities:

- (a) the improper use of trademarks (in particular, the Examiner pointed to paragraphs [00070], [00074], [00089], [000102], [0055] and [000120]); and
- (b) the paragraph numbers appear to be incorrect (i.e., [00010] should be [0010]).

In response to (a), paragraphs [0055], [0070], [0074], [0085], [00086], [00089], [000102] and [000106] have been amended herein to capitalize all trademarks and add the necessary markings to each. While the Examiner noted paragraph [000120] in the objection, no trademarks were identified in such paragraph, and therefore such paragraph was not amended herein.

In response to (b), Applicant respectfully traverses this objection. 37 CFR 1.52(b)(6) clearly states that paragraph numbers "should consist of **at least four** numerals enclosed in square brackets..."; this clearly does not require that the paragraph number only contain four numerals, but rather covers paragraph numbering containing **more than four** numerals, as occurs in the subject application. Therefore, Applicant respectfully submits that the objection to the disclosure as outlined in (b) above is improper.

In response to (4) above, claims 6, 7, 68 and 82 have been canceled herein, without prejudice, and therefore the objection thereto has been rendered moot. Claims 37 and 51 have been amended herein to change "Pan-Class I" to "pan-Class I", as required by the Examiner.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the objections to the disclosure and claims.

Applicants' Response to the 35 U.S.C. 112, ¶ 1

(Written Description) Rejection

In the Office Action, the Examiner rejected claims 3, 4, 33, 34, 64 and 65 under 35 U.S.C. 112, first paragraph (written description). In support thereof, the Examiner stated that "the specification does

not convey to the artisan that the Applicants had possession at the time of invention of the claimed an assay or method or kit for detecting the presence of anti-HLA antibodies in a sample wherein the solid support used in the assay or method or present in the kit is a combination of solid supports such as those recited in the instant claims."

Claims 3, 4, 64 and 65 have been canceled herein, without prejudice, and therefore the rejection of such claims has been rendered moot.

In response to the rejection of pending claims 33 and 34, such claims have been amended herein to remove the "combinations thereof" language from the Markush group recited in claim 33.

Therefore, Applicants respectfully submit that pending claims 33 and 34 fully comply with the 35 U.S.C. 112, first paragraph, written description requirement. Applicants respectfully request reconsideration and withdrawal of such rejection of pending claims 33 and 34.

Applicants' Response to the 35 U.S.C. 112, ¶1 (Enablement) Rejection

In the Office Action, the Examiner rejected Applicants' claims 3, 4, 7, 21, 33, 34, 37, 64, 65, 68 and 2 under U.S.C. 112, first paragraph (enablement). With regard to claims 3, 4, 33, 34, 64 and 65, the Examiner stated that the Specification does not disclose how to

make and use the invention, "wherein the solid support used in the assay or method or present in the kit is a combination of solid supports such as those recited in the instant claims". With regard to claims 7, 21, 37, 68 and 82, the Examiner stated that "the instant specification does not disclose a repeatable process to obtain the hybridoma that produces W6/32, and it is not apparent if the hybridoma or monoclonal antibody is readily available to the public".

Claims 3, 4, 7, 21, 64, 65, 68 and 82 have been canceled herein, without prejudice, and therefore the rejection of such claims has been rendered moot.

Regarding claims 33 and 34, as stated herein above, such claims have been amended to remove the language related to combinations of solid supports from the Markush claim 33.

Regarding claim 37, paragraph [0081] has been amended herein to include the biological deposit information for antibody W6/32, thus demonstrating that such biological material is known and readily available to the public. The Federal Circuit has established that "the addition of information designating the depository, accession number, and deposit date of the deposited cell line in ATCC after the filing date [does] not violate the prohibition against new matter in 35 U.S.C. 132." *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). Therefore, Applicants respectfully submit that the amendment to

paragraph [00081] is proper and does not constitute new matter. Entry of such amendment to the Specification is respectfully requested.

Further, attached hereto as Exhibit A is a listing from the website of AbD Serotec (Kingston, NH), which lists eight W6/32 products as commercially available. Also attached thereto is the datasheet for the first product listed. These eight products range in price from \$237 - \$336. Therefore, Applicants also respectfully submit that W6/32 is commercially available from at least one supplier.

Therefore, Applicants respectfully submit that claims 33, 34 and 37 fully comply with the enablement requirement of 35 U.S.C. 112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, ¶1 (enablement) rejection of pending claims 33, 34 and 37.

Applicants' Response to the 35 U.S.C. 112, ¶12 Rejection

In the Office Action, the Examiner rejected Applicants' claims 1-7, 12-17, 19-21, 30-37, 42-51, 60-68, 73-82, 91 and 92 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 1-7, 12-17, 19-21, 30, 43-44, 60-68, 73-82, 91 and 92 have been canceled herein, without prejudice, and therefore Applicants respectfully submit that the rejection thereof has been rendered moot.

The Examiner stated that claim 34 was included in this rejection because it contained the trademarks/trade names LUMINEX and DYNABEADS, and such claim has been amended herein to remove said trademarks/trade names.

The Examiner stated that claims 31, 32, 35, 36, 42 and 50 were rejected as being indefinite for reciting "individual, soluble HLA molecule", and the Examiner further stated that "it is not clear what is meant, i.e., if it is just one HLA molecule or multiple copies of one HLA allele product". Such claims have been amended herein to recite "a pool of individual soluble MHC trimolecular complexes". Therefore, Applicants respectfully submit that such amended claims are definite.

The Examiner stated that claim 37 was rejected for being indefinite for reciting "W6/32". Applicants respectfully submit that based on the amendments to the Specification and for the reasons stated above in response to the 35 U.S.C. 112, ¶1 (enablement) rejection, the recitation of "W6/32" is not simply a laboratory designation but is clearly a given name for a particular product, as evidenced not only by biological deposit thereof at ATCC, but also by

the commercial availability thereof under such given name. Therefore, Applicants respectfully submit that claim 37 is definite.

Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, second paragraph, rejection of pending claims 31-37, 42 and 45-51.

Applicants' Response to the Prior Art Rejections

In the Office Action, the Examiner rejected claims 1-7, 12, 13, 30-37, 42, 43, 60 and 61 under 35 U.S.C. 102(b) as being anticipated by US 5,482,841; and claims 1-7, 12, 13, 30-37, 42, 43, 60 and 61 under 35 U.S.C. 102(e) as being anticipated by US5,482,841. The Examiner also rejected Applicants' claims 1-7, 12, 13, 30-37, 42, 43, 60-68, 73-82, 91 and 92 under 35 U.S.C. 103(a) as being unpatentable over US5,482,841 in view of US5,292,641; and claims 1-7, 12, 13, 30-37, 42, 43, 60-68, 73-82, 91 and 92 under 35 U.S.C. 103(a) as being unpatentable over US5,482,841 in view of US5,292,641, Prilliman et al. (Immunogenetics, 45:379-385 (1997)), DiBrino et al. (Biochemistry, 34:10130-10138 (1995)) and US6,232,445.

As stated herein above, the only remaining independent claim is claim 31, and such claim has been amended herein to include all of the limitations of dependent claim 44. Claim 44 was not included in any of

the 35 U.S.C. 102/103 rejections issued by the Examiner. Therefore, Applicants respectfully submit that claim 44 is free of the prior art.

Thus, Applicants respectfully submit that independent claim 31, as well as claims 32-42 and 45-51 which depend there from are not anticipated by nor obvious over the prior art cited in the 35 U.S.C. 102/103 rejections. Applicants respectfully request reconsideration and withdrawal of all of the 35 U.S.C. 102/103 rejections of the claims as currently pending.

Applicants' Response to the Provisional Obviousness-Type

Double Patenting Rejection

In the Office Action, the Examiner provisionally rejected claims 62-68, 73-82, 91 and 92 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-34, 39-44, 46-52, 54-56, 57-63, 68-73, 75-81 and 83-112 of copending Application No. 10/902,400 in view of US5,482,841.

Such claims have all been canceled herein, without prejudice, and therefore Applicants respectfully submit that the provisional obviousness-type double patenting rejection has been rendered moot.

Applicants' Response to the Examiner's Assertion Regarding  
the Filing Date of the Application

In the last paragraph on Page 9 of the Office Action, the Examiner stated that: "for the purpose of prior art rejections, the filing date of the instant claims is deemed to be the filing date of the instant application, i.e., 9/24/03, as the parent applications do not support the claimed limitations of the instant application".

Applicants respectfully strenuously traverse the Examiner's assertion, and respectfully submit that the parent applications more than amply disclose the presently claimed invention. Thus, Applicants respectfully submit that the subject application is entitled to the benefit of the filing date of the parent applications.

## **CONCLUSION**

This is meant to be a complete response to the Office Action mailed March 23, 2007. Applicants respectfully submit that each and every objection to the disclosure and claims, as well as each and every rejection of the claims, has been overcome. Further, Applicants respectfully submit that pending claims 31-37, 42 and 45-51, as now amended, are free of the prior art of record and are in a condition for allowance. Favorable action is respectfully solicited.

In addition, claims 38-41 are currently withdrawn; however, upon allowance of any of claims 31-37, 42 and 45-51, Applicants respectfully request rejoinder and reconsideration of currently withdrawn claims 38-41. In addition, the Examiner previously required election of a single disclosed species to be used in the claimed method (i.e., a specific substrate, soluble HLA molecule, antibody and anchoring moiety). Upon allowance of any of claims 31-37, 42 and 45-51, Applicants respectfully request rejoinder and reconsideration of all disclosed and claimed species (i.e., all specific substrates, soluble HLA molecules, antibodies and anchoring moieties).

Should the Examiner have any questions regarding this amendment, or the remarks contained therein, Applicants' representative would welcome the opportunity to discuss the same with the Examiner.

Respectfully submitted,



Kathryn L. Hester, Ph.D.  
Registration Number 46,768  
DUNLAP, CODDING and ROGERS, P.C.  
Customer No. 30589  
P.O. Box 16370  
Oklahoma City, Oklahoma 73113  
Telephone:(405) 607-8600  
Facsimile:(405) 607-8686  
E-Mail: kathryn\_hester@okpatents.com  
Web Site: www.okpatents.com  
Agent for Applicants